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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/736,545 | 12/17/2003 | Masahiro Kawaguchi | 03500.017338 | 6817 |
| 5514 | 7590 | 09/09/2005 | | EXAMINER |
| FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | | LIU, SUE XU |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1639 | |

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/736,545 | KAWAGUCHI ET AL. |
| | Examiner | Art Unit |
| | Sue Liu | 1639 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1, drawn to a product of DNA microarray, classified variously, for example in class 435, subclass 6.
 - II. Claims 2-7, drawn to a product of DNA microarray, classified variously, for example in class 435, subclass 6.
 - III. Claim 8, drawn to a product of a primer set for PCR, classified variously, for example in class 536, subclass 24.3.
 - IV. Claims 9 and 10, drawn to a kit comprising primer sets, classified variously, for example in class 536, subclass 24.3.
 - V. Claims 11-12, drawn to a kit comprising external standard nucleic acids, classified variously, for example in class 536, subclass 24.3.
 - VI. Claim 13, drawn to a kit comprising nucleic acid derived from microorganism or virus, classified variously, for example in class 536, subclass 24.32.
 - VII. Claims 14-19, drawn to a product of DNA microarray, classified variously, for example in class 435, subclass 6.
 - VIII. Claims 20-25, drawn to a method of analyzing DNA microarray, classified variously, for example in class 435, subclass 6.
 - IX. Claim 26, drawn to a method of producing a DNA microarray, classified variously, for example in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions in Groups VIII and IX direct to distinct methods, because they use different steps, require different reagents and/or will produce different results. The invention of Group VIII directs to a method of analyzing DNA microarray, and Group XI directs to a method of making a DNA microarray. Each of the method has materially different function, modes of operation, and different effects. For example, Group VIII method requires using ion mass spectrometry, which are step and/or reagent that are not required by Group XI. Thus, inventions of Groups VIII and IX are distinct, and restriction between the groups is proper.

Inventions of Groups I-VII are unrelated and represent patentably distinct products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions of Groups I-VII are drawn to distinct products because they differ in respect to their properties, their use and/or method of making. Groups I, II and VII are drawn to different DNA microarrays; Group III is drawn to a set of primers; And Groups IV-VI are drawn to different kits. Each category (microarrays; primers; kits) of products is different from each other and represents separate and distinct products, because they possess different functions and/or structures. Within each category, the recited product of each Group is different and distinct from each other. For example, Group I product of

a DNA microarray requires “probes added for quantitative evaluation of the amount or density of said nucleic acid...”, which is not required by any other Groups. Group II invention of a DNA microarray requires “internal and/or external standard nucleic acids are added in order to quantitatively determine a concentration of the target...” which is not required by any other groups. Group VII DNA microarray requires “the first set of nucleic acid probe dots...” which is not required by any other groups. Group IV product is drawn to a kit comprising primer sets that are not required by Group V or VI kit. Group V kit requires markers, which are not required by Group IV or VI. Art anticipating or rendering obvious each of the above identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I-VII have different issues regarding patentability and enablement and represent patentably distinct subject matter. Thus, restriction is proper.

Inventions of Groups (VIII and IX), and Groups I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Groups I-IX direct to various methods and products as aforementioned. Each of the products from Groups I-VII can be used in or made by a materially different process or method from the ones recited in Groups VIII and IX. For example, each of the microarrays directed in Groups I, II and VII can be produced by a materially different method such as solid phase synthesis on microbeads. Thus, restriction between the groups is proper.

Therefore, these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. The different methods and products will require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches will be coextensive. Therefore, these do create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

3. This application contains claims directed to the following sets of patentably distinct species of the claimed invention. Applicants are requested to further elect a single ultimate species for each of the following:

- A.) A single ultimate species of a marker. (e.g. fluorescent markers.)
- B.) A single number of external standard probes on a microarray. (e.g. 2 kinds of external standard probes.)
- C.) A single number of internal standard probes on a microarray.
- D.) A single specific species of a probe. (e.g. single-stranded DNA.)
- E.) A single specific chain length specified for all probes on a microarray. (e.g. 20 residues for Internal Standard probes; 30 residues for External Standard probes; etc.)
- F.) A single specific number of primer sets with specific amplification product lengths. (e.g. 2 sets of primers that will produce 500 bp and 200 bp products.)
- G.) A single specific species of a microorganism. (e.g. HIV.)

H.) A single specific number of nucleic acids derived from the elected microorganism.
(e.g. 2 nucleic acids.)

I.) A single specific number of external standard nucleic acid. (e.g. 2.)

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purpose as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PADMASHRI PONNALURI
PRIMARY EXAMINER

Sue Liu
Art Unit 1639
9/02/05